JAN 14 1987

Hutzel Hospital
ATTN: Ray Carlson
Medical Physicist
4707 St. Antoine
Detroit, MI 48201

Dear Mr. Carlson:

We have reviewed your letter dated October 30, 1986 requesting an amendment to License Number 21-03001-01 and find that we will need additional information as follows:

1. In order to add James E. Selis, M.D. as a user of radionuclides, he must document the number of hours he received in clinical radioisotope training on the Preceptor Statement, Supplement B, Item 3. He must have at least 500 hours of training. In addition, if he wishes approval for Group III, he must document experience eluting a Mo/Tc99m generator at least 5 times and preparing at least 5 reagent kits.

2. If Stephan J. Loginsky, M.D. wishes approval for Group III, he must submit evidence of experience eluting a Mo99/Tc99m generator at least 5 times and preparing reagent kits 5 times.

3. Please describe Dr. Jack Sobel's experience and training handling radioactive material. List the radionuclides with which he has experience and the approximate quantities used.

4. Please provide a description of the in vitro laboratory facilities in Hutzel Hospital Annex Building. Identify the rooms by room number and describe the equipment available.

5. It is not practical to list all manufacturers of bone densitometers and gadolinium-153 sources. Therefore, specify by name and model number the bone densitometers you wish to receive.

6. Describe who will perform maintenance of the bone densitometer involving the shutter or shutter control mechanisms. We recommend these services be performed by the manufacturer other or other persons licensed by the NRC who have specific training.

7. Reference the source changing procedures that you will follow by manufacturer, document name, and date, e.g., Lunar User's Manual dated.... You may instead submit a copy of the procedure.

8. Confirm that personnel performing gadolinium-153 source installations and removals will be monitored with finger badges.

9. Drs. Han, Ahmad and Kim will be approved for Group VI procedures based on their certification by the ABR in Therapeutic Radiology. However, if they wish to use radiopharmaceuticals in Groups I through V they must submit Supplements A and B forms with all of the items completed. The training documented must meet the criteria as described in the Federal Register Notice, Volume 47, No. 232 dated December 2, 1982 (copy enclosed).

10. Regarding Donald G. Bronn, M.D. he also must submit the information stated in Item 9 above to be approved for Groups I through V. To be approved for Group VI he must either obtain the necessary certification as described in Table I of the referenced Federal Register Notice or submit letters of evaluation from each preceptor describing the scope and extent of his training, and should state whether in the opinion of the preceptor, the applicant is fully qualified. These letters and his Supplement A and B forms will be submitted to the NRC's Advisory Committee on the Medical Uses of Isotopes for their review. This procedure takes several months.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 82396.

Sincerely,

Original Signed By
Evelyn R. Matson
Materials Licensing Section

Enclosure: Criteria for
Physician-Users

RIII
Matson/pd
1/14/87